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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/828, 143 03/24/97 HSIA

H 24400-101

	EXAMINER
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HM22/0208

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MARY, I	PAPER NUMBER
ART UNIT	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/828,143	Applicant(s) Hsia
	Examiner Irene Marx	Group Art Unit 1651

Responsive to communication(s) filed on Dec 21, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 9-11, 16-20, and 24-35 is/are pending in the application.

Of the above, claim(s) 9-11 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 16-20 and 24-35 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/00 has been entered.

Claims 16-20 and 24-35 are being considered on the merits. Claims 9-11 are withdrawn from consideration.

Double Patenting

Claims 16-20 and 24-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-24 of copending Application No. 08/879220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications are directed to substantially the same nutritional composition comprising bacteria, yeast and protein in a certain overlapping ranges.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-20 and 24-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claims 16 and 33 "wherein the viability of the bacteria in the composition does not decrease for a period of at least ten months when the composition is stored in an airtight container", in claim 20 for "wherein the viability of the bacteria in the composition does not decrease for a period of at least twelve months when the composition is stored in an airtight container", in claim 26 and 34 for "wherein the viability of the bacteria in the composition does not decrease for a period of at least eighteen months when the composition is stored in an airtight container"

No basis or support is found in the present specification for the recitation of "dry" weight in claims 16-20 and 24-32.. In the specification at page 9, lines 19-25 the percentage is based on the total mass of the mixture composition. No indication of dry or wet weight is found.

Therefore, this material raises the issue of new matter and should be deleted.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that there is support for the lack of decrease in viability at the table in Example 2, and page 10, lines 16-20. However, Example 2 pertains exclusively to the viability of the bacterial composition of Example 1 and not to unidentified bacteria, yeast or protein as claimed for an unlimited period of time, that includes decades and centuries. Moreover, the disclosure at page 10, lines 16-20 pertains to the protein source and is not informative regarding the issue at hand..

The basis of applicant's assertions that one having ordinary skill in the art of food preparation would at the time the claimed invention was made have understood that "% of total mass" used in the application and claims to mean the "% dry weight of the dry compositions" is not set forth (Response, page 5, paragraph 2). That the composition of example 1 is comprised of specific ingredients provided by one or more commercial sources is not dispositive of whether one of ordinary skill in the food art would or would not mix bacteria, yeast and protein prior to freeze drying, for example. Similarly, providing ingredients that are "dried" in a composition comprising a mixture of ingredients cannot be construed as meaning that all of the components are necessarily weighed after drying.

It is also of interest to note that the original claims 3 and 7 are directed to certain percentages of the "total mass" of the composition. There is nothing on the record to fairly suggest to one of ordinary skill in the art that the correct interpretation of this recitation is "percent dry weight".

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Levy (EP 430736) in light of Prescott *et al.* for the reasons as stated in the last Office action and the further reasons below.

Applicant's contentions regarding the amounts used by Levy are noted. However, the invention as claimed fails to identify the type of bacteria, yeast or protein to be used for the methods. Therefore, there is no reason to conclude, for example, that the "protein" component necessarily must be non-yeast or non-bacterial, and the amounts may be calculated accordingly.

Applicant's arguments regarding lack of disclosure in Prescott of yeast as being particularly "concentrated source of protein" is puzzling. It is unclear what applicant considers to be a particularly concentrated source of protein. In the present written disclosure applicant fails to define with any specificity what is intended by a "protein concentrate". Therefore, the standard

to be applied to ascertain whether a given protein does or does not constitute a "protein concentrate" is uncertain in the present disclosure. The degree of concentration is not defined with any particularity. In addition there is no indication in the present specification as-filed that applicant intended to exclude yeast protein as a concentrated form of protein, whether or not this is so disclosed by Prescott.

Applicant's emphasis on what is shown in the examples of Levy appears misplaced, considering that the invention as claimed is not based with any specificity on the example herein.

Also, Levy appears to use live cultures, since the purpose of the bacteria is to restore balance to the intestinal flora by slowing the multiplication of undesirable microorganisms (page 2, col. 1). The reference also recognizes the favorable interactions between specific bacteria and yeast, which are termed "synergistic" in their effects on humans and animals. Applicants also argue that the Levy reference fails to address survivability over time. Yet the material as claimed bears little relationship to the composition that has been demonstrated to retain viability, in Example 2, i.e., the bacterial composition of Example 1, while the material claimed to maintain viability for an unlimited period of time comprises unidentified bacteria, yeast and protein. Regarding "viability", there is nothing on the record to suggest that the tablets of Levy are subject to a decrease in viability that is greater than that of applicant's composition. Inasmuch as the nature of the bacteria, yeast and protein are substantially the same, viability can be presumed to be substantially the same, whether or not this property is or is not explicitly disclosed.

Applicant's attention is also directed to the new matter rejection *supra* regarding the touted viability properties of the as claimed composition.

Therefore the rejection is deemed proper and it is adhered to.

Claims 16-20 and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy taken with Prescott *et al.*, Jolly, Friend and El-Megeed *et al.*.

Applicants' arguments have been fully considered but they are not deemed to be persuasive.

Applicants' arguments directed to demonstrated new properties of a food additive are irrelevant to the as claimed invention (response, page 12) et seq.

Applicants argue the viability of the bacteria in the composition does not decrease for a period of at least ten months when the composition is stored in an airtight container. Yet there is nothing on the record to provide basis or support for this claim, as noted in the rejection under 35 U.S.C § 112, regarding new matter. Applicants have demonstrated stability up to 18 months with a specific composition containing commercial grade components in specific amounts, wherein the viable bacteria are *Lactobacillus acidophilus*, the yeast is debittered brewer's yeast and the protein is soy protein isolate (Example 1, page 12). There is nothing on the record to demonstrate or fairly suggest that the tablets of Levy are subject to a decrease in viability that is greater than that of applicant's composition. Inasmuch as the nature of the bacteria, yeast and protein that constitute the composition of the invention are not claim designated, they do not appear to be critical elements of the invention.

As to the arguments that the yeast material is intended to provide nutrients for the *Lactobacillus*, applicants have not indicated when the nutrients are to intended be used by the solid, dried, viable *Lactobacillus*. Applicant argues the merits of prolonging viability of *Lactobacillus* (Response, page 16, paragraph 1). Yet the claims are directed to "bacteria", except for claim 18, which recites a variety of bacteria that actually include *Lactobacillus* in the grouping. Therefore, these arguments are not persuasive of error in the rejection.

The stable preparation shown in the specification at page 12, Example 1, contains a large amount of soy protein, and the amount of yeast is greater than the amount of *L. acidophilus*. There is no clear correlation between this example and the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well

known in the art for their claimed purpose and for the reasons outlined *supra*. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of Levy, Prescott *et al.*, Jolly, Friend and El-Megeed *et al.*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants have not demonstrated any unexpected properties of the composition as claimed.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Claims 33-35 are allowable over the art of record because the compositions disclosed in the prior art of record do not fairly disclose or suggest a stable, dried bacterial composition containing about 0.7 dry weight percent solid, dried, viable *L. acidophilus*, about 5.3 dry weight percent dried, non-living yeast and about 92.3 dry weight percent soy protein isolate. There would have been no motivation for one of ordinary skill in the art to modify the compositions of the prior art relating to products containing bacteria, yeast and protein in the manner claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651